EXHIBIT 11

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN THE MATTER OF IN RE BAIR HUGGER FORCED AIR WARMING PRODUCTS LIABILITY LITIGATION Plaintiff, v. 3M COMPANY AND ARIZANT HEALTHCARE INC. Defendant.	)))))))PRETRIAL ORDER NO: 7)Protective Order)MDL No. 15-2666)(JNE/FLN)))

DEPOSITION OF PAUL MCGOVERN
VOLUME II
Thursday, January 5, 2017
AT: FAEGRE BAKER DANIELS LLP
Taken at:
7 Pilgrim Street
London EC4V 6LB
United Kingdom

Court Reporter:
Louise Pepper: Accredited Real-time Reporter
Videographer: Simon Addinsell

JOB NO. 117121

lights, in my research, has a marked effect on particle concentration. The use of forced-air warming device -- devices, in my experience, has an influence on particle counts near the operative site, particularly when combined with overhead operating lights. And the presence of -- the number of people in the operating room, as well as their movement, influences it. The amount of kit, the heat emitted by the kit, the amount -- the type of surgery, because some surgeries produce particles: if you're operating on bone, then dust is produced. Sometimes there can be mists from electrocautery machines, from other equipment. Fluids can spray. All these things can influence airflows and particle counts in the region of the operative field.

Q. Okay. Are you aware that deep joint infection rates in operating rooms increased in the late 1980s up until the 2000s?

A. I am aware --

MR. C. GORDON: Object to the form of the question. Assumes facts not in evidence.

A. I'm aware that studies have shown that, or have indicated that.

BY MR. SACCHET:

Q. Do you think, given your experience in orthopedic

operating rooms and your knowledge of laminar airflow, that laminar airflow is the culprit of the rising infection rates from the 1980s to 2000?

MR. C. GORDON: Same objection.

A. Laminar airflow in itself?

BY MR. SACCHET:

Q. Yeah.

A. I do not.

Q. Do you think that forced-air warming, which I believe you mentioned just a couple of minutes ago, has impacted the rising infection rate during that time period?

MR. C. GORDON: Same objections.

A. I believe it's possible.

BY MR. SACCHET:

Q. You've encountered a lot of orthopedic surgeons who are concerned about the use of forced-air warming in orthopedic procedures; correct?

A. That is correct.

MR. C. GORDON: Please note a form objection.

BY MR. SACCHET:

Q. The Bair Hugger is a forced-air warming system; correct?

A. Yes.

Q. The filter of the Bair Hugger is on the bottom of

the device?

A. I believe -- I think there are various designs of Bair Hugger blower devices, and I'd need to look at one to confirm exactly the location of the filter. I don't remember.

Q. Have you ever seen a Bair Hugger with a filter on the bottom?

A. I've seen many Bair Huggers, Bair Hugger blower units, and I remember the control panels and what they look like, but I don't remember where -- if the filter was on the bottom or the side.

Q. Whether it's on the bottom or the side, the device is often placed on the ground of the operating floor?

A. Can I clarify: are you asking where the exhaust -- the blower unit is, or the intake is?

Q. The intake.

A. Yeah, the intake. I can't remember where the intake is. You asked if --

Q. Whether the blower itself is often placed on the floor?

A. It will be placed on a -- generally, on a stand which is very close to the floor. So less than a foot from the floor, generally.

Q. So whether the filter is on the side of the device

or under the device, it's taking in air close to floor level; correct?

MR. C. GORDON: Object to the form of the question.

A. Generally, yes.

BY MR. SACCHET:

Q. And some of that air bypasses the filter; correct?

MR. C. GORDON: Object to the form of the question. Lack of foundation.

A. It depends on the specific filter unit, and I do not know if that's always the case. It's possible that air bypasses the filter, but I don't know what proportion of it does.

BY MR. SACCHET:

Q. You were a co-author on a paper that dealt with filtration efficiencies; correct?

A. I was, yes.

Q. And that paper, which we'll talk about later, found that the air filtration efficiency of the model 700 Bair Hugger blower was approximately 63 percent; correct?

A. It did find that, yes.

Q. So if that's the filtration efficiency at the -- at let's say 0.2 microns, some particles are then passed through the filter; correct?

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A. Yeah, if the filtration efficiency is reduced, then some particles which the filter is intended to block are passing through that filter. That is how I understand that result.

Q. If some of those particles had bacteria on them that bypassed the filter, the bacteria could colonize inside the blower?

A. It's possible, yes.

Q. You're not aware of any other filters on the device beyond the intake filter, are you?

A. I am not. I don't have an intimate knowledge of the anatomy of a Bair Hugger blower unit, but I'm not aware of further filtration stages.

Q. You've never seen a filter at the hose end of the device?

A. No, that's correct.

Q. And you've never seen a filter inside the blanket?

A. That's correct.

Q. So it's possible that particulates or bacteria could pass through the blanket?

MR. C. GORDON: Object to the form of the question. Lack of foundation.

A. It is possible.

BY MR. SACCHET:

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Q. It's also possible, and in fact you have been in correspondence suggesting the same, that a large percent of the heat from the blower does not enter the body but is exhausted into the operating room; correct?

MR. C. GORDON: Object to the form of the question.

A. I do believe that, yes.

BY MR. SACCHET:

Q. More than 800 watts of what I'll say waste heat can enter the operating room from the Bair Hugger; correct?

MR. C. GORDON: Object to the form of the question. Lack of foundation; assumes facts not in evidence.

A. Yes, all the power of a blower unit, all of the heat is going into the operating room in some form. Even if it goes into the patient, there's a -- the patient is within the operating room as well. So, a proportion of heat will go into the operating room. A proportion of heat energy will go into the operating room, yes.

(Exhibit 2 marked for identification)

Q. I'm just going to try to refresh your recollection for a moment with the document that's being marked.

A. Thank you.

Q. If you could turn to page 3 of 3.

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A. Yes.

Q. The last e-mail is dated July 3, 2010, from you.

A. Yes.

Q. To Mark Albrecht?

A. Yes.

Q. In the penultimate paragraph, the e-mail states:

"The energy paper has a nice bit on the significantly higher efficiency of Augustine CWB than Arizant FAW."

What does "Augustine CWB" mean?

A. "Augustine" refers to the company, I believe Augustine Biomedical & Design, and "CWB" refers to, I think, conductive warming blanket.

Q. And is "Arizant FAW" likely the Bair Hugger?

A. "Arizant FAW" refers in this e-mail to the Bair Hugger device.

Q. You continue:

"I think the message can still be put strongly in the terms you mentioned i.e. FAW is inefficient and has a high power draw ask (compared with CWB), resulting in a potential loss into the OR environment in excess of 800W."

So would you agree that in some cases, the Bair Hugger does result in excess heat of 800 watts of

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energy?

A. Yes.

MR. C. GORDON: Object to the form of the question: lack of foundation, assumes facts not in evidence.

A. Yes.

BY MR. SACCHET:

Q. So whether by blowing air in the operating room, or allowing air through the blanket, it's possible that the Bair Hugger moves bacteria toward the surgical site; correct?

MR. C. GORDON: Object to the form of the question: lack of foundation, calls for speculation, incomplete hypothetical.

A. It is possible.

BY MR. SACCHET:

Q. You have demonstrated this effect with respect to bubbles in a number of videos that were posted on a blog for Northumbria; correct?

A. That's correct.

Q. One of those videos is this one, which I'll play for you, and counsel is welcome to walk around and watch it if he pleases. I have DVDs that can be marked the same.

(Exhibit 3 marked for identification)

Q. I'll play it first, and then we can talk about it.

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THE VIDEOGRAPHER: Do I need to record this?

MR. SACCHET: I'm not entirely sure how to do that. The sound will come through, so you will be able to hear it on the video, and it can be transcribed the same way.

(Audio from DVD):

"In this clip, the forced-air warming blanket is turned on and the light is positioned under laminar flow to illuminate the operative field. The majority of the contaminated air from beneath the drapes is cleared by laminar flow. However, potentially contaminated air can be seen in the disrupted laminar flow underneath the operating light. At this stage, very little contaminated air is seen in front of the surgeon in the region of the operative field. The presence of the anaesthetist further disrupts the laminar flow, allowing hot air from the forced-air warming blanket to rise. Within 10 seconds, there is an increase in the contaminated air underneath the operating light. Less than 20 seconds after the anesthetist stands in front of the patient, there is a clear increase in contaminated air in front of the surgeon and in the region of the operative field."

MR. C. GORDON: Is that the whole --

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MR. SACCHET: That's the whole clip.

MR. C. GORDON: Did you just excerpt it yourself?

MR. SACCHET: No, this was taken directly from the production.

MR. C. GORDON: And that was the entire thing that was on the --

MR. SACCHET: This is entitled "The final demonstration of FAW." I think it is labeled on the envelope I gave you. And you're welcome to look at it later and determine that this is the accurate copy of such.

(Reporter clarification.)

MR. SACCHET: It's labeled on the --

A. "The accurate copy of such."

BY MR. SACCHET:

Q. Mr. McGovern, do you have any doubt that that is the full and complete copy of the video?

A. No, I recognize that as the video that I produced and placed on the Northumbria orthopedics blog.

Q. Did you narrate the video?

A. I did.

Q. Were you the anesthesiologist that appeared next to the screen?

A. I was taking the role of the anesthesiologist in that video, yes.

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Q. Was Mr. Reed the individual in the spacesuit?

A. Yes.

Q. To the extent anything was not evidenced by the narration that you provide, can you provide a quick summary of what was observed in the video?

A. What that video shows is a set-up in which a mannequin is placed on an operating table as though -- and prepared as though for surgery, in terms of surgical draping. A Bair Hugger blanket is placed over the mannequin in the position that it usually would be for surgery. And the drapes have been positioned to fashion an anesthesia screen which takes the form of surgical drapes being clipped to a higher level, which often happens in operating rooms; the idea being to slightly reduce the chance of any spatter from the operative site going on to the anesthetist or their equipment. The forced-air warming blanket is turned on in that clip, and the bubble generator discussed yesterday is active. The outlet of the bubble generator is near the head end of the simulated patient.

What the clip shows is that with the operating lights in a position which they may well be, to illuminate an operative field, the presence of the anesthetist, in combination with the position of the operating light, in combination with the energy emitted

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by the forced-air warming blanket, encouraged particles -- or encouraged, in this case, neutral density helium bubbles -- from the region of the patient or the model patient's head to find their way up, the front of the anesthetist, along the operating lights, and down into the region of the operative field.

Q. Were standard particles performed with respect to draping and placement of the patient and the Bair Hugger, and any other steps that were performed in the simulation?

A. The draping, the positioning of the Bair Hugger, the position of the operating lights, the position of the anesthesia screen, were all designed -- were all intended to replicate those which would be seen in a real operation.

Q. Mr. Reed supervising is in fact in the simulation; correct?

A. Could you repeat that, please?

Q. Mr. Reed supervised and was in fact present in the simulation?

A. That's correct. Mr. Reed was -- yeah, supervised the positioning of the patient and the draping, and the positioning of the Bair Hugger, and the position of the operating lights, and the positioning of the anesthetist, and of the operating table.

Q. He had no concerns about the set-up?
A. None that I'm aware of.
Q. And you used bubbles in this video; correct?
A. That's correct.
Q. Bubbles are a type of particle; right?
A. The bubbles are, I would agree, a type of particle.
Q. And, as we discussed before, with respect to your toga study and other papers that have been published, particles can be a measurement of bacteria?
A. That is the assumption that we are using and that is the inference we are drawing when we are measuring particles and measuring bubbles in these experiments.
Q. So, if bubbles are a type of particle, and particles can measure bacteria, presumably the bubbles were attempting to measure bacteria; correct?
A. The bubbles were attempting to demonstrate the way air flows. Bubbles are not -- they are more a measure of where air flows, and they show where air has flown from and to. The inference, therefore, is that particles would be carried on the airflows, and the bubbles enable us to visualize where air starts and where air ends up. And so, the inference that we took from that experiment was that air was flowing from the area of the patient's head, a non-sterile zone, to what was considered a sterile zone, and

that any light, airborne particles, we assumed would have been carried along that air current.
Q. And air generated from a non-sterile zone could have bacteria?
A. That's correct.
Q. And so it's possible that some of the particles that were being demonstrated through bubbles could have had bacteria on them?
A. Absolutely correct.
Q. You've posted other videos showing the same effect?
A. A similar effect, yes.
Q. Have you ever heard of another medical device, other than the Bair Hugger, that takes in air from the floor area and blows it on to a patient?
A. There is, I believe, a dressing gown type apparatus which performs a similar role, the idea of it being to warm a patient before or after surgery, when they're sitting in a chair. And I believe that uses similar blower technology but has a different form of blanket.
Q. Is that the Bair Paws?
A. I think it may be. I've not used one myself, but I know of their existence. We discussed yesterday -- sorry, could you just repeat the question that you asked? Any?
Q. There's another medical device that sucks in air

from near the floor area and blows it on to the patient during a surgery?
A. During surgery? No.
Q. No?
A. Not to my knowledge, no.
Q. So, when you were previously discussing the gown that could be worn, that may have a similar purpose, that's used in pre and post?
A. I don't know how it's used. I don't know if people would use that during surgery. I don't have any experience of that. I believe that's compatible with the Bair Hugger forced-air warming blower units, but I haven't seen it used. I'm aware of its existence.
Q. Isn't the fact that the Bair Hugger is blowing air on to the patient inimical to the purpose of laminar airflow?
MR. C. GORDON: Object to the form of the question.
A. It potentially compromises what is a very fragile system. Laminar airflow is far more fragile than, I think, many people believe, and warm air blowing in the region of laminar airflow can, in my opinion, disrupt laminar airflow, especially if the conditions are correct to do it, such as if laminar airflow is blocked by overhead operating lights

or other equipment, or surgeons, or any other thing in the way of the laminar airflow.
BY MR. SACCHET:
Q. And speaking of fragility, the situation is also very fragile because just us single bacterium could cause a deep joint infection; correct?
A. Correct.
Q. So, over a hour-long surgery or more, all it takes is one bacterium from air disruption, as a result of the Bair Hugger, to cause a surgical site infection?
A. That is possible.
Q. Have you seen the recent guidance from the Healthcare Infection Control Practice Advisory Committee regarding water heater-cooler devices?
A. Regarding?
Q. Water heater-cooler devices.
A. I have not.
Q. So unfortunately I only have two copies of this document, so Mr. Head and Mr. Gordon can potentially share, or Mr. Head can share with Mr. McGovern.
MR. C. GORDON: Is it about the heater-cooler units?
MR. SACCHET: Yeah.
MR. C. GORDON: I don't need that.

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A. Thank you.

Q. This is a initial e-mail from Mr. Albrecht to yourself on May 19, 2011; correct?

A. Yes.

Q. He says, "See reviewer's comments below (only minor)."

A. Yes.

Q. Below that is an e-mail from -- actually a letter from James Scott, an editor of the journal?

A. Yes.

Q. To Mr. Albrecht?

A. Yes.

Q. It says:

"Thank you for submitting your paper for consideration by the Journal of Bone and Joint Surgery. It has been reviewed by experts in the field and by members of the editorial staff";

Does it not?

A. It does.

Q. On the third page of this e-mail there are comments from reviewer 2, correct? Which is designated on the second page but carrying over on to the third page?

A. Correct.

Q. In the first full paragraph, the reviewer states:

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"The second part of the paper is a study of the infection in the cases done in their unit over a period of years before, during and after the transition from the forced-air warming apparatus to the conductive material heating apparatus."

Do you see that?

A. I do.

Q. The reviewer goes on to state:

"This demonstrates that there were actual changes in infection rates which would fit well with the experimental data and therefore support the contention that there is a serious issue to be addressed with some of the warming devices."

Do you see that?

A. I do.

Q. Does that refresh your recollection that one of the editors of the Journal of Bone and Joint Surgery said that the study supported serious issues with respect to warming devices?

A. One of the peer reviewers said that.

Q. One of the peer reviewers?

A. Yes.

Q. Yesterday you were asked about some of the potential limitations of the study; correct?

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A. Yes.

Q. You were asked about particular patient demographics?

A. Yes.

Q. And table 1 of the study itself shows that some patient-specific demographics were similar between the patient groups who received forced-air warming versus conductive fabric warming; correct?

A. Yes.

Q. And table 2 shows that, as to those particular patient-specific demographics, including age, diabetes and length of pre-operative stay, that they did not significantly impact infection rates; correct?

A. That is what I understand from this data.

Q. With regard to other potential patient-specific demographics, including things like obesity, or incontinence, or fitness for surgery, do you have any reason to doubt that the two patient groups between forced-air warming and conductive fabric warming were different?

A. No.

Q. This data was observational in nature; right?

A. Correct.

Q. Observational data is a legitimate scientific methodology; correct?

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MR. C. GORDON: Object to the form of the question.

A. It is -- well, data is not a methodology.

BY MR. SACCHET:

Q. Studies.

A. But observational studies are legitimate scientific studies, in my opinion.

Q. In the absence of a randomized controlled study, observational studies are considered to be the next best alternative; correct?

A. I wouldn't know if they were the next best alternative, but they are a valuable component of the total body of knowledge on a subject.

Q. Are you aware that in other healthcare circumstances, such as the use of tobacco and cancer rates, that for a very long period of time there was never a randomized controlled trial that proved causation between the use of tobacco and cancer?

A. Absolutely, yes.

Q. And all that there was to rely on for many, many years, were observational studies?

A. Absolutely, yes.

Q. And we all know, beyond peradventure, that tobacco causes cancer?

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objection, please.

MR. C. GORDON: Form.

A. That is what this data appears to show.

BY MR. SACCHET:

Q. So this data shows there is a 3.6 times increase in infection as a result of using forced-air warming devices compared to conductive fabric warming devices; correct?

A. That is what --

MR. C. GORDON: Object to the form of the question.

A. That is what this table appears to show.

BY MR. SACCHET:

Q. And both this odds ratio and the odds ratio presented in the final published McGovern study are both above 3.0; correct?

A. Yes.

Q. So, based on this data in the increased patient population of those who received conductive fabric warming, this data corroborates the fact that there is at least a three times more likely chance that patients who received forced-air warming developed an infection, compared to those who received conductive fabric warming?

MR. C. GORDON: Object to the form of the question.

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A. This data -- I can't agree with the term "corroborates the fact". The fact is not --

BY MR. SACCHET:

Q. Also shows?

A. Yeah. Could you just repeat the phrase, please, or rephrase that? Or --

Q. I'll rephrase the question.

Based on the data presented in this table and the data presented in the McGovern study, both studies for both datasets show that there was a three -- at least a three times more likely chance that a patient developed an infection after using forced-air warming than conductive fabric warming?

MR. C. GORDON: Object to the form of the question.

A. Yes. Patients who were in the group with forced-air warming on this data appear to have had a three times or more higher incidence of infection compared to the conductive fabric group of patients for this study.

THE COURT REPORTER: Can I just ask you to stop for 30 seconds, sorry.

THE VIDEOGRAPHER: Going off at two minutes past three.

(3:02 p.m.)

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(Break taken.)

(3:04 p.m.)

THE VIDEOGRAPHER: Back on the record at four minutes past three.

(Exhibit 24 marked for identification)

BY MR. SACCHET:

Q. Mr. McGovern, are you aware of any data that's been collected regarding other healthcare facilities that have shown a decreased rate of infection after the switch from forced-air warming devices to conductive fabric warming devices?

A. I am not.

Q. If you could take a look at the exhibit which was just marked. The first page is an e-mail; is that correct?

A. Yes.

Q. From Mr. Albrecht to Scott Augustine, bearing the subject line "Results" with attachments "MA_edits"; correct?

A. Yes.

Q. And Mark Albrecht states:

"I've updated the statistics in the white paper under **MA_edits.doc**."

A. Yes.

Q. "The updates include:

"The statistics in the Table for all centers and

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the pooled result[s]

"The statistics in the discussion for the updated McGovern numbers provided as provided [sic] in the text."

Do you see that?

A. Yes.

Q. In the third paragraph it says:

"I think this is the best modeling approach (i.e. a conservative one) for the data you have, especially if you expect these results to be critically questioned down the road."

Do you see that?

A. Yes.

Q. Okay. And the next page is a document entitled "Forced-air warming link to periprosthetic total joint replacement infections"; correct?

A. Yes.

Q. And the "Methods" says:

"To investigate whether the rising contaminants from the waste FAW heat are linked to PJIs, we retrospectively collected joint implant infection data from three hospitals. We compared PJI rates during a period of forced-air warming to PJI rates during a period of free-air conductive fabric